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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,562	07/06/2001	Katie Mary Binley	9192.16USWO	3021

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EXAMINER
CHEN, LIPING

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 09/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/787,562	Applicant(s) BINLEY ET AL.	
	Examiner Liping Chen	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-27 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-15, 17-27 and 31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Election/Restriction

Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or goups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. Claims 1-5, 8-10, 12-15 and 20-22, drawn to a polynucleotide comprising at least two repeats of a hypoxia response element (HRE) having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a nucleic acid of interest (NOI) encoding HIF-1, a vector, and a host cell.

II. Claims 6, 7 and 11, drawn to a polynucleotide comprising at least three repeats of a phosphoglycerate kinase HRE having SEQ ID NO:3 (or SEQ ID NO:4, or SEQ ID NO:5).

III. Claims 1, 9, 10,12, 15 and 17, drawn to a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a NOI encodes a polypeptide which is cytotoxic, and a host cell.

IV. Claims 1, 9, 10, 12, 15 and 18, drawn to a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a NOI encodes a polypeptide capable of converting a precursor into a cytotoxic compound, and a host cell.

V. Claims 1, 9, 10, 12, 15 and 19, drawn to a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID

NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a NOI encodes a proteins involved in the regulation of cell division, and a host cell.

VI. Claims 1, 9, 10, 12, 15 and 19, drawn to a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a NOI encodes an enzyme involved in cellular metabolic pathways, and a host cell.

VII. Claims 1, 9, 10, 12, 15 and 19, drawn to a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a NOI encodes a transcription factor, and a host cell.

VIII. Claims 1, 9, 10, 12, 15 and 19, drawn to a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a NOI encodes a heat shock protein, and a host cell.

IX. Claims 1, 9, 10, 22-25, 27 and 31, drawn to a retroviral vector comprising a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11) and a nucleotide sequence encoding an inhibitory RNA molecule capable of effecting the cleavage of VHL, and a method of producing a viral strain comprising introducing the polynucleotide into the genome of retrovirus.

X. Claims 1, 9, 10, 22-24, 26 and 31, drawn to an adenoviral vector comprising a polynucleotide comprising at least two repeats of a HRE having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the HIF consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11) and a nucleotide sequence encoding an inhibitory RNA molecule capable of effecting the cleavage of VHL (or inhibitory RNA molecules that bind to and prevent VHL RNA processing, or polypeptide capable of inhibition the binding of VHL to Elongin B or C), and a method of producing a viral strain comprising introducing the polynucleotide into the genome of adenovirus.

This application Groups I-X contain claims directed to more than one distinct invention. They are:

Groups I and III-X contain distinct invention as follow:

Different HRE/promoter structure: SEQ ID NO: 1, SEQ ID NO:2, or SEQ ID NO:9; (elect one)

For each elected HRE SEQ ID, a further election is required for SEQ ID for spacer:

SEQ ID NO:10 or SEQ ID NO:11 (elect one)

Group II contains claim directed to more than one distinct invention. They are:

Different HRE/promoter structure: SEQ ID NO:3, SEQ ID NO:4, and SEQ ID NO:5 (elect one)

Groups IX and X further contain claims directed to more than one distinct invention. They are different nucleotide sequences encoding different RNA or polypeptide for enhancing HRE response:

1) an inhibitory RNA molecule capable of effecting the cleavage of VHL,

2) an inhibitory RNA molecules that bind to and prevent VHL RNA processing,

3) a polypeptide capable of inhibition the binding of VHL to Elongin B or C or both

(elect one)

These are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. Applicant is required to select one species for examination practice.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I encompasses a polynucleotide comprising at least two repeats of a hypoxia response element (HRE) having SEQ ID NO:1 (or SEQ ID NO:2, or a HRE/promoter having SEQ ID NO:9), wherein the hypoxia-inducible factor (HIF) consensus binding sites within each of the two repeats are separated by a spacer having SEQ ID NO: 10 (or SEQ ID NO:11), a nucleic acid of interest (NOI) encoding HIF-1, a vector, and a host cell. Groups II-X are directed to different products for different use that require different special technical features as summarized as follows: Group II is directed to distinct polynucleotide constructs containing SEQ ID NO:3, 4, or 5; Groups III-VIII each encoding a structurally functionally independent gene product for distinct cell population such as a cytotoxic polypeptide, a polypeptide capable of converting a precursor into a cytotoxic compound, a protein involved in the regulation of cell division, an enzyme involved in cellular metabolic pathways, a transcription factor or a heat shock protein, respectively, each construct requires a specific technique feature to be used in each cell population; Groups IX and X each directed to modify a retroviral vector or an adenoviral vector and the associated virus, respectively, by introducing nucleotide encoding structurally and functionally independent RNA or polypeptide to enhance HRE response. The HRE and HIF were well-known in the art, as evidenced by Webster et al. (5,834,309, issued 11/10/98). Thus, Groups I-X lack a common special technical feature. Further, 37 CFR 1.475 does not provide for multiple independent products, methods of manufacture and methods of use (37 CFR 1.475(d). Therefore, The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liping Chen, whose telephone number is (703) 305-4842. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time). Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Pauline Farrier, Patent Analyst, at (703) 305-3550. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Liping Chen, Ph.D.
Patent Examiner
Group 1632
September 6, 2002

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